K060530

Y 22 2006

510(K) SUMMARY AND CERTIFICATION
[As required by 21 CFR 807.92(c)]

1. Submitter's Name and Contact Person

Lifecore Biomedical, Inc. 3515 Lyman Blvd Chaska, MN 55318	Rachel Kennedy Regulatory Affairs Manager Ph: 952-368-6294; Fax: 952-368-4278

2. General Information

Trade Name	Lifecore PrimaConnex™ Ceramic Coping
Common Name	Ceramic coping
Classification Name	Porcelain tooth
Identification of Predicate Devices	• Procera® Copings and Pontic (Nobel Biocare USA Inc.) (K032562)

3. Device Description

Lifecore Biomedical PrimaConnex Ceramic Copings are pre-manufactured for use as a core structure in the construction of single-unit cement retained restorations. The Ceramic Copings will be offered in three sizes; Small Diameter (SD), Regular Diameter (RD), and Wide Diameter (WD) to fit with the corresponding PrimaConnex Quick-Abutments, previously cleared under K051614. The Ceramic Coping contains an internal flat for anti-rotation and is cemented onto the Quick-Abutment after completion of the prosthetic restoration.

The Ceramic Copings are manufactured from Yttria-Stabilized Tetragonal Zirconia (Y-TZP) in conformance with ISO Standard 13356, *Implants for Surgery – Ceramic Abutments Based on Yttria-Stabilized Tetragonal Zirconia (Y-TZP).*

4. Intended Use

PrimaConnex Ceramic Copings are intended for use as a core structure for a prosthetic restoration in partially or fully edentulous mandibles and maxillae, in the construction of single-unit cement retained restorations.

5. Substantial Equivalence Comparison

The PrimaConnex Ceramic Copings are substantially equivalent to the predicate devices. All copings are intended for use as a core structure for a prosthetic restoration. The subject and predicate devices are intended for single use only. The Lifecore PrimaConnex Ceramic Copings are similar in fundamental scientific technology to the predicate devices in that they incorporate equivalent coping designs, materials, and intended use. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the PrimaConnex Ceramic Copings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2006

Ms. Rachel Kennedy
Regulatory Affairs Manager
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318

Re: K060530
Trade/Device Name: PrimaConnex™ Ceramic Copings
Regulation Number: 21 CFR 872.3920
Regulation Name: Porcelain Tooth
Regulatory Class: II
Product Code: ELL
Dated: February 27, 2006
Received: February 28, 2006

Dear Ms. Kennedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

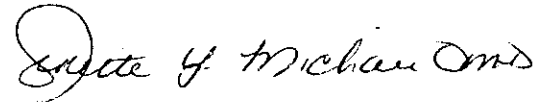
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: PrimaConnex™ Ceramic Copings

Indications for Use:

PrimaConnex Ceramic Copings are intended for use as a core structure for a prosthetic restoration in partially or fully edentulous mandibles and maxillae, in the construction of single-unit cement retained restorations.

The copings are designed to fit Lifecore's PrimaConnex Quick-Abutment.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Div...Off)
...n of Anesthesiology, General Hospital,
...on Control, Dental Devices

...Number K060530